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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte DAVID P. BINGAMAN, ABBOT F. CLARK,
RAJNI JANI and STELLA M. ROBERTSON,

Appellants

Appeal 2009-010169
Application 10/772,963
Technology Center 1600

Decided: 29 April 2010

Before SALLY GARDNER LANE , *Lead Administrative Judge,* RICHARD TORCZON, and MICHAEL P. TIERNEY, *Administrative Patent Judges.*

LANE, *Lead Administrative Patent Judge.*

DECISION ON APPEAL

I. STATEMENT OF THE CASE

The appeal, under 35 U.S.C. § 134, is from a Final Rejection of claims 1 and 3-18. Appellants canceled claim 2. (App. Br. 2). We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

Appellants' specification relates to treatment for pathologic ocular angiogenesis, which is the formation of new blood vessels in the eye. (Spec. p. 1, ll. 4-12).

The Examiner relied on the following patent documents:

Name	Number	Date	Abbreviation
Boltralik	4,686,214	August 11, 1987	Boltralik
Clark	5,371,078	December 6, 1994	Clark
Peyman	5,516,522	May 14, 1996	Peyman
Billson	WO 95/03807	February 9, 1995	'807

Appellants appeal the following rejections:

- claims 1, 3-5, and 8-18 under 35 U.S.C. § 103(a) over Clark and Peyman;
- claims 1, 4-5, and 16-18 under 35 U.S.C. § 103(a) over Clark and WO 95/03807; and
- claims 1, 3, and 6-7 under 35 U.S.C. § 103(a) over Clark and Boltralik.

Appellants did not argue for the separate patentability of any of the claims within these rejections by using a separate heading. To the extent Appellants address claims dependent on claim 1, we discuss these issues below, but we focus on claim 1 in our review of each rejection. *See* 37 C.F.R. § 41.37(c)(vii).

II. FINDINGS OF FACT

1. Appellants' claim 1 recites[1]:

> A method for treating pathologic ocular angiogenesis and any associated edema which comprises, administering a composition comprising
> an effective amount of a glucocorticoid and
> an effective amount of anecortave acetate.

(App. Br. 11; Claims App'x).

2. Clark teaches angiostatic steroids, that is, steroids that inhibit angiogenesis, and their use in controlling hypertension in the eye, such as in glaucoma. (Clark col. 2, ll. 62-66).

3. The Examiner finds, and Appellants do not dispute, that the angiostatic steroids taught in Clark include anecortave acetate (which is also referred to as 4,9(11)-pregnadien-17α,21-diol-3,20dione-21-acetate (*see* Spec. p. 8, ll. 13-14)). (Clark col. 3, l. 1, through col. 6, l. 42; *see also* Clark claim 2).

4. Peyman teaches that it was known to treat neovascularization with "steroids with antiproliferative effects." (Peyman col. 7, ll. 55-58).

5. Peyman teaches that it was known to treat proliferative vitrioretinopathy ("PVR") with, among other drugs, glucocorticoids such as predinisone, prednisolone, and fluorometholone. (Peyman col. 7, ll. 33-55).

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[1] Claim 1 has been modified by adding an indentation. *See* 37 C.F.R. § 1.75(i).

6. Appellants' specification provides that the glucocorticoids useful in the claimed method include prednisone, prednisolone, and fluorometholone. (Spec. p. 4, ll. 10-13).

7. The Examiner finds, and Appellants do not dispute, that PVR is an "ocular angiogenesis-associated disorder." (Ans. 3).

8. '807 teaches that triamcinolone acetonide is useful for treating age-related macular degeneration. ('807 abstract and p. 2, ll. 2-3, and p. 3, ll. 4-5).

9. Appellants' specification provides that the glucocorticoids useful in the claimed method include triamicinolone acetonide. (Spec. p. 4, ll. 10-13).

10. Appellants' specification provides that age-related macular degeneration is a pathologic ocular angiogenic condition within the scope of the claimed method. (Spec. p. 11, ll. 7-11).

11. Boltralik teaches that a compound the Examiner identifies, and Appellants do not dispute, to be rimexolone, is useful in treating patients with open angle glaucoma. (Boltralik col.2, ll. 25-38, and col. 4, ll. 3-5).

12. Appellants' specification provides that the glucocorticoids useful in the claimed method include rimexolone. (Spec. p. 4, ll. 10-13).

13. Appellants' specification provides that chronic glaucoma is a pathologic ocular angiogenesis-related condition within the scope of the claimed method. (Spec. p. 11, ll. 7-11).

III. ISSUE

Would it have been obvious to combine a glucocorticoid known to be useful in treating pathologic ocular angiogenesis and anecortave acetate,

which was also known to be useful in treating pathologic ocular angiogenesis, to achieve a treatment for the same condition?

IV. ANALYSIS

Appellants claim a method of treating pathologic ocular angiogenesis by administering a composition comprising a glucocorticoid and anecortave acetate. (FF[2] 1).

Appellants do not dispute that Clark teaches anecortave acetate as a treatment for ocular angiogenesis. (*See* FF 3).

Peyman, '807, and Botralik each teach administering glucocorticoids to treat ocular disorders that Appellants do not dispute, and acknowledge in their specification, are angiogenesis-related disorders. (FFs 4-13).

Appellants' main argument against the obviousness of the claimed method is that "[t]he question is not whether using two different compounds to treat pathologic ocular angiogenesis is obvious, but rather, whether using two different compounds in the same composition is obvious." (App. Br. 5). "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition which is to be used for the very same purpose." *In re Kerkhoven*, 626 F.2d 846, 850 (CCPA 1980). Appellants have not provided evidence to persuade us that those of skill in the art would not have learned from the prior art that the individual ingredients were known to treat ocular angiogenesis-related disorders or that the combination of the ingredients would do the same. *Contra Gillette Co. v. S.C. Johnson & Son, Inc.*, 919

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[2] "FF" indicates a Finding of Fact.

F.2d 720 (Fed. Cir. 1990) (holding a composition of chemicals to be non-obvious because the composition forms a post-foaming shaving gel when none of the individual compounds, though known in the art, was known to form a post-foaming shaving gel). Appellants have not provided evidence that those of skill in the art would have been incapable of combining the teachings of Clark with the other prior art references. Accordingly, we are not persuaded that the composition would not have been obvious.

According to Appellants, the device for drug delivery taught in Peyman was intended to be used with one agent, so that Peyman provides only a suggestion to try using a combination of active agents. (App. Br. 6). Appellants do not provide evidence for this assertion. "Argument of counsel cannot take the place of evidence lacking in the record." *Meitzner v. Mindick*, 549 F.2d 775, 782 (CCPA 1977). Furthermore, Peyman was not cited for teachings regarding the delivery device. It was cited to show that those of skill in the art knew before Appellants' filing date that glucocorticoids have antiproliferative effects and were known to be useful for treating an ocular angiogenesis-associated disorder. (*See* FFs 6-8). Thus, this argument is unpersuasive.

Appellants also argue that it would not have been known by those in the art that administering a glucocorticoid with a second antiangiogenic agent would prevent unwanted side effects that occur with the glucocorticoids alone. (App. Br. 6-7). In a related argument, Appellants assert that Boltralik teaches away from using an agent in addition to a glucocorticoid because Boltralik does not teach side effects of glucocorticoids. (App. Br. 9).

Appellants do not recite reducing side effects of glucocorticoids in their claimed method. Thus, whether or not the method incurs side effects has no bearing on it patentability. Furthermore, "[i]n determining whether the subject matter of a patent claim is obvious, neither the particular motivation nor the avowed purpose of the patentee controls . . . . Under the correct analysis, any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed." *KSR Int'l v. Teleflex Inc.*, 550 U.S. 398, 419-20 (2007). Even if those of skill in the art would not have known that the combination would reduce the side effects of glucocorticoids alone, that the ingredients are individually useful for the same purpose renders the combination *prima facie* obvious. *See Kerkhoven*, 626 F.2d at 850.

To the extent that Appellants argue there are unexpected results from the claimed method because it was known that glucocorticoids produce significant side effects (*see* App. Br. 6-7), they do not provide sufficient evidence to support that those of skill in the art would not have expected this result or even that the claimed method reduces side effects. *See Meitzner,* 549 F.2d at 782; *see also* App. Br. 13, Evidence App'x: "None."

Finally, Boltralik does not teach away from the claimed method. Appellants do not point to, and we do not find, any teaching in Boltralik that would have discouraged those in the art from adding rimexolone to a glucocorticoid to treat pathologic ocular angiogenesis. "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the

reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994).

Appellants also argue that Peyman does not teach doses of steroids that would be successful for treating pathologic ocular angiogenesis. (App. Br. 5). Appellants' claim 1 is not limited to a composition with any specific dose of glucocorticoid. Thus, we are not persuaded that the teaching of glucocorticoids in Peyman does not fall within the scope of Appellants' claim 1.

To the extent that Appellants' dependent claims recite percentages of glucocorticoids, Peyman teaches that delivering an effective concentration of therapeutic agents is one of the "major limiting factors" of successful treatment. (*See* Peyman col. 4, ll. 64-67). "[D]iscovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. . . . It is well settled that a prima facie case of obviousness may be rebutted 'where the results of optimizing a variable, which was known to be result effective, (are) unexpectedly good.'" *In re Boesch*, 617 F.2d 272, 276 (CCPA 1980) (quoting *In re Antonie*, 559 F.2d 618, 618-620 (CCPA 1977). Appellants have not provided sufficient evidence that the concentrations of glucocorticoids recited in dependent claims 5, 7, 9, 11, and 13 would have been considered to be unexpectedly good by those in the art. Accordingly, Appellants have not persuaded us that the claimed concentrations are not obvious.

V. CONCLUSION

It would have been obvious to combine a glucocorticoid and anecortave acetate, both known to be useful in treating pathologic ocular

angiogenesis, to achieve a treatment for the same condition. Thus, the Examiner did not err in rejecting Appellants' claims under 35 U.S.C. § 103(a).

VI. ORDER

Upon consideration of the record and for the reasons given,

the rejection of claims 1, 3-5, and 8-18 under 35 U.S.C. § 103(a) over Clark and Peyman is AFFIRMED;

the rejection of claims 1, 4-5, and 16-18 under 35 U.S.C. § 103(a) over Clark and WO 95/03807 is AFFIRMED; and

the rejection of claims 1, 3, and 6-7 under 35 U.S.C. § 103(a) over Clark and Boltralik is AFFIRMED.

FURTHER ORDERED that no time period for taking any subsequent action in connection with the appeal may be extended under 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

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